



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Thomas SPIES and Veronika SPIES

Group Art Unit: 1644

Serial No.: 09/855,612

Examiner: A. DeCloux

Filed: May 4, 2001

Atty. Dkt. No.: FHCC:003USC1/SLH

For: CELL STRESS REGULATED HUMAN  
MHC CLASS I GENE

CERTIFICATE OF MAILING  
37 C.F.R. § 1.8

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*[Signature]*

INVENTORS' DECLARATION UNDER 37 C.F.R. § 1.131

Hon. Commissioner for Patents  
Washington, D.C. 20231

Thomas Spies and Veronika Spies each declare that:

1. I am one of the named joint inventors on the above-captioned application.
2. It is my understanding that the Amendment and Response to the Office Action Dated March 11, 2003 ("Response") contained arguments traversing an enablement rejection of the claims. In that Response, it was stated, "The presence of MICA and MICB in astrocytoma and colon carcinoma cell lines, as supported by page 75, lines 6-9 and page 76, lines 24-25, which clearly show that MICA and MICB are associated with a wide variety of cancers (see above)." Response at page 6.

3. However, it is my opinion that expression of MICA and MICB in tumor cell lines is not necessarily indicative of cancer because MICA and MICB expression is frequently induced in rapidly proliferating cell lines commonly used in a laboratory.

4. Nonetheless, the observation of expression of MICA and MICB in freshly isolated tumor cell suspensions, as discussed in the paper of Groh *et al.*, (1999), was indicative of cancer. Such evidence is also relied on by the argument offered in the Response, which cites the Groh *et al.* paper. This reference reports that freshly isolated tumor specimens from carcinomas of the lung, breast, kidney, ovary, prostate and colon express MICA and MICB. As stated in the Response, this evidence supports the claimed invention.

5. I hereby declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

7/28/03  
Date

Thomas Spies  
Thomas Spies, Ph.D.

7/28/03  
Date

Veronika Spies  
Veronika Spies, M.D.